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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,394	12/12/2005	Carl Gustav Figdor	ALXN-PO1-095	6059

28120 7590 06/02/2009

ROPES & GRAY LLP
PATENT DOCKETING 39/41
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
06/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,394	FIGDOR ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19, 21, 23,-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19, 21, 23,-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

On further consideration, the finality of the rejection of the last Office action is withdrawn. Applicants' amendments filed on 04/28/2009 and 05/06/2009 are entered. Claim 19, 21, and 23-30 are pending and under consideration.

Withdrawn Objections and/or Rejections

The rejection of claims 33-41 under 35 U.S.C. 112, first paragraph for written description is moot by canceled claims.

The rejection of claims 19 and 22-41 under 35 U.S.C. 112, first paragraph for scope of enablement is withdrawn in view of amended claim 19 and canceled claims 22 and 31-41.

The rejection of claims 26 and 39 under 35 U.S.C. 112, second paragraph is withdrawn in view of amended claims.

Sequence Compliance

A paper copy of Sequence Listing and a computable copy of the Sequence Listing submitted on 05/06/2009 have been received by the office.

Claim Rejections under 35 USC § 112, 1st paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 19, 21, 24, 25, and 29-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for enriching the percentage of macrophages in a synovial sample of cells using an antibody that binds to the DC-SIGN protein that has the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for a method for enriching the percentage of macrophages in a sample of cells using an antibody that binds to DC-SIGN. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 19, 21, 24, 25, and 29-30 are drawn to a method for enriching the percentage of macrophages in a sample of cells from a person with a rheumatoid arthritis. The claims encompass any samples of cells from a person with a rheumatoid arthritis. The specification discloses that DC-SIGN, an ICAM-3 binding C-type lectin, is preferentially expressed by dendritic cells. On page 17 (paragraph [0082]), the specification discloses that DC-Sign is expressed by a large subpopulation but not by all synovial macrophages/dendritic cells. The specification also discloses that a large percentage of macrophage cells in the synovium of rheumatoid arthritis patients can be used to purify such macrophage cells (paragraph [0089]). However, the specification fails to provide sufficient guidance and working examples with respect to enriching the percentage of macrophages in samples of cells other than a synovial sample from a rheumatoid arthritis patient. The Example 6 of FACS analysis of five rheumatoid arthritis patients shows that >95% of cells were CD14 positive monocytes, but does not show the detection of DC-SIGN positive macrophages (page 23).

The prior art teaches that DC-SIGN is specifically expressed by dendritic cells (US 7,148,329 B1; Table 1). Soilleux et al. teach that peripheral blood mononuclear cells and monocyte-derived macrophages were consistently negative for DC-SIGN expression under a variety of standard culture conditions (J. Leukoc. Biol. 71:445-457, 2002; page 446, left column, the 3rd paragraph). It is unpredictable whether a reasonable amount of DC-SIGN positive macrophages are present in the peripheral blood sample or other type of samples other than a synovial sample from a rheumatoid

arthritis patient. It would take a large amount of experimentation to determine whether any given samples of cells obtained from a rheumatoid arthritis patient comprise a reasonable amount of DC-SIGN positive macrophages that can be used to enrich the percentage of macrophages.

Moreover, claim 25 recites "the method of claim 19 wherein said macrophage expresses CD68". From the instant disclosure (page 17, paragraph [0082]), it appears that all DC-SIGN positive macrophages express CD68. The specification does not disclose any DC-SIGN positive macrophages that do not express CD68.

For the reasons above, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim Rejections under 35 USC § 112, 2nd paragraph

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 19, 21, and 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite because they recite the acronym, "DC-SIGN". First, such a term is determined arbitrarily without a definitive structure. Others in the field may isolate the same protein and give an entirely different name. Thus, claiming biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what the protein is. Applicants should particularly point out and distinctly claim the DC-SIGN protein by claiming characteristics associated with the protein, such as a sequence identifier (SEQ ID NO).

Claim Objection

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 25 recites "wherein said macrophages express CD68", which does not further limit the macrophage in claim 19 because DC-SIGN positive macrophages express CD68 (see page 17, paragraph [0082] of the instant specification).

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

May 31, 2009